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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,122	11/12/2003	Jurgen Brinkhues	9003-286US	6214
570 7590 04/12/2007 AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103			EXAMINER MEHTA, BHISMA	
			ART UNIT 3767	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/706,122		BRINKHUES, JURGEN	
	Examiner		Art Unit	
	Bhisma Mehta		3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>01/10/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to mention the annular continuous sealing zone being directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film. In paragraphs [0011], [0012], and [0044], the sealing zone is described as directly adjoining or being adjacent to the edge of the inert film but there is no reference to the sealing zone being in continuous abutting contact with an entire outer circumferential edge of the inert film.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnaughey (U.S. Patent No. 2,895,773) in view of Pharma Gummi Wimmer West GmbH (EP 0 148 426) ("Pharma Gummi"). In Figure 3, McConnaughey shows a piston stopper comprising a one-piece rubber base body (307) with a receiving cavity (310) for connecting with a displacement transferring element (320) and a piston section (302a). The outer circumference of the piston section (302a) abuts against a syringe cylinder

Art Unit: 3767

(320) as seen in Figure 3a. The piston stopper has an uncoated sealing section which includes sections (302b and 302c) adjacent to the piston section (302a) and which abuts flat against the syringe cylinder (320). At least one continuous sealing tip (302b) and an annular continuous sealing zone (302c) are provided on the outer circumference of the sealing section. At least a portion of the sealing zone (302c) is provided as a straight extension to an outer circumference of the piston section (302a) and abuts against a syringe cylinder (320) or slightly projects beyond a portion of the outer circumference of the piston section (302a). In Figure 3, McConnaughey show a section of an inside wall of the piston stopper with an internal thread (304b) to connect with a thread (322b) of the displacement transferring element (320) where the internal thread (304b) terminates at a spacing from a bottom (306) of the receiving cavity (310). The section with the internal thread (304b) terminates at the piston section (302a) or at a spacing from it and a cylindrical or tapered receiving cavity (at 321c in Figure 3a) extends between the internal thread (304b) and the section of the receiving cavity (310) which extends into the piston section (302a). As seen in Figure 3a, a cross-section of the receiving cavity (310) tapers out from the bottom (306) of the receiving cavity toward an opening of the receiving cavity. McConnaughey discloses the piston stopper substantially as claimed. However, McConnaughey is silent on the piston section being enclosed in a cap-shaped inert film where the film comprises a fluorinated polymer film. In Figure 18, Pharma Gummi show a rubber piston stopper (33) having multiple sealing lips (34, 35, 36) and, in lines 3-10 of page 29, Pharma Gummi teach enclosing a piston section (37) of the piston stopper in a cap-shaped inert film (8) comprising a fluorinated

polymer film. It would have been obvious to one having ordinary skill in the art at the time the invention was made to enclose the piston section of McConnaughey in a cap-shaped inert film such as a fluorinated polymer film as taught by Pharma Gummi as Pharma Gummi teach that it is well known to provide an inert film on a piston section of a piston stopper which is facing the contents of a syringe cylinder to avoid unwanted interaction between the contents of the syringe cylinder and the rubber portion of the piston stopper (see line 16 of page 8 to line 10 of page 9).

The annular continuous sealing zone (302c) of McConnaughey includes at least a portion of the section (303a) and so the sealing zone is considered to be directly adjacent to and in continuous abutting contact with the lower portion of the piston section (302a). It should be noted that by enclosing the piston section (302a) of McConnaughey with the inert film (8) of Pharma Gummi, the annular continuous sealing zone (302c) of McConnaughey would be directly adjacent and in continuous abutting contact with an entire outer circumferential edge of the inert film. The inert film of Pharma Gummi would be placed on the piston section (302a) in the same manner as is shown in Figure 18 of Pharma Gummi where the inert film is on the piston section (37). With regards to Figure 3 of McConnaughey, the inert film of Pharma Gummi would be placed on the piston section (302a) such that the lower edge or portion of the inert film would be at the section (303a) which is considered to be part of the annular continuous sealing zone (302c), thus this sealing zone would be directly adjacent to and in continuous abutting contact with an entire outer circumferential edge of the inert film.

Response to Arguments

4. Applicant's arguments with respect to claims 15-20 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

